

NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and the agency decides to make substantial changes to the rule after it is proposed, the agency must prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, and the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R06-205]

PREAMBLE

1. Register citation and date for the original Notice of Proposed Rulemaking:

Notice of Proposed Rulemaking: 12 A.A.R. 1156, April 14, 2006

2. Sections Affected

R4-23-402

Rulemaking Action

Amend

3. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. § 32-1904(B)(5)

4. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@cox.net

5. An explanation of the rule, including the agency's reasons for initiating the rule:

During the January 25, 2006, Board meeting, Board President Chuck Dutcher instructed Board staff to craft proposed rules to require the documentation of the name or initials of the pharmacist, graduate intern, or pharmacy intern who does or does not provide oral consultation on a new prescription. The Board feels that the existing rule is flawed because it does not require the identification of the person who does or does not counsel. The rulemaking will amend R4-23-402 (Pharmacist, Graduate Intern, and Pharmacy Intern) by adding language to subsection (H) requiring documentation of the identity of the pharmacist, graduate intern, or pharmacy intern who does or does not provide oral consultation on a new prescription. The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of this rule will benefit the public and the pharmacy community by clearly establishing the standards for patient counseling provided by pharmacists and pharmacy interns and graduate interns under pharmacist supervision.

6. An explanation of the substantial change which resulted in this supplemental notice:

At the Board's June 26, 2006 meeting, the Board approved changes to R4-23-402(A)(10 and (15). The changes to R4-23-402(10) will specify the processes a pharmacist or graduate intern or pharmacy intern under a pharmacist's supervision must follow when checking prescription order data entry to ensure that the data input is correct for patient, drug, directions, and medical practitioner. The new language in R4-23-402(A)(10) will specify the items that must be verified for accuracy. The changes to R4-23-402(A)(15) will remove the requirement to manually initial a new prescription order received by facsimile, computer modem or other means of communication. Since the requirement became effective in November 2000, pharmacists have had difficulty complying with the initialing requirement because in most cases, a technician first receives and processes a facsimile or computer-generated prescription. A

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pharmacist sees the facsimile or computer-generated prescription after initial processing, and by then it seems pointless to add a pharmacist's manual initial. After six years of trying to enforce this provision, the Board has decided that the pharmacist's manual initials are not necessary on a facsimile or computer-generated new prescription order. The Board feels new language in R4-23-402(A)(15) that requires a pharmacist or graduate intern or pharmacy intern under pharmacist supervision to verify that a completed prescription medication is sold only to the correct patient, patient's care-giver, or authorized agent is necessary and appropriate. The Board receives numerous consumer complaints that involve a pharmacy selling a patient's prescription medication to the wrong patient, usually the patient names are the same or similar. The changes to R4-23-402(A)(10) and (15) are substantive, and the Board will have a public hearing to allow the public to comment on the changes.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The amended rule will impact the Board, pharmacies, pharmacists, pharmacy interns, graduate interns, and the public. The amended rule's impact on the Board will be the usual rulemaking-related costs, which are minimal. The Board estimates the amended rule will have minimal economic impact on pharmacies, pharmacists, pharmacy interns, and graduate interns. The amended rule has no economic impact on the public.

The public, Board, pharmacies, pharmacists, pharmacy interns, and graduate interns benefit from rules that are clear, concise, and understandable. The amended rule benefits the public and the pharmacy community by clearly establishing the standards for pharmacist, graduate intern, and pharmacy intern duties, including patient counseling provided by pharmacists and pharmacy interns and graduate interns under pharmacist supervision.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302
Telephone: (623) 463-2727, ext. 131
Fax: (623) 934-0583
E-mail: rxcop@cox.net

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, July 24, 2006. An oral proceeding is scheduled for:

Date: July 24, 2006
Time: 10:00 a.m.
Location: 4425 W. Olive Ave., Suite 140
Glendale, AZ 85302
Nature: Public Hearing
Close of record: 5 p.m. on July 24, 2006

A person may request information about the oral proceeding by contacting the person listed in item #9.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the changes follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section

R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

- A.** No change
1. No change
 2. No change
 3. No change
 - a. No change
 - b. No change
 4. No change
 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 6. No change
 7. No change
 8. No change
 9. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 10. Check a prescription label order data entry to ensure that the data input:
 - a. Is for the correct patient by verifying the patient's name, address, telephone number, gender, or date of birth or age;
 - b. Is for the correct drug by verifying the drug name, strength, and dosage form;
 - c. Communicates the prescriber's directions precisely by verifying dose, dosage form, route of administration, dosing frequency, and quantity; and
 - d. Is for the correct medical practitioner by verifying the medical practitioner's name, address, and telephone number.
 11. No change
 12. No change
 13. No change
 - a. No change
 - b. No change
 - c. No change
 14. No change
 - a. No change
 - b. No change
 - c. No change
 15. Verify, and manually initial a new prescription order received by, or assume responsibility to verify, that a completed prescription medication is sold only to the correct patient, patient's care-giver, or authorized agent
 - a. ~~Facsimile,~~
 - b. ~~Computer modem, or~~
 - c. ~~Other means of communication;~~

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- 16. No change
- 17. No change
- B.** No change
 - 1. No change
 - 2. No change
 - 3. No change
- C.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- D.** No change
 - 1. No change
 - 2. No change
 - 3. No change
- E.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- F.** No change
- G.** No change
- H.** Oral consultation documentation. When oral consultation is required as specified in subsection (B), a pharmacist, graduate intern, or pharmacy intern shall:
 - 1. Document, or assume responsibility to document, that oral consultation is provided; or
 - 2. When a patient refuses oral consultation or a person other than the patient or patient's care-giver picks up a prescription and oral consultation is not provided, document, or assume responsibility to document, that oral consultation is not provided; or
 - 3. When a pharmacist, graduate intern, or pharmacy intern determines to omit oral consultation under subsection (D) and oral consultation is not provided, document, or assume responsibility to document, both the circumstance and reason that oral consultation is not provided; and
 - 4. Document, or assume responsibility to document, the name, initials, or identification code of the pharmacist, graduate intern, or pharmacy intern who did or did not provide oral consultation.
- I.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- J.** No change
- K.** No change
- L.** No change